K122402

JUL 16 2013

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Date Prepared: July 15, 2013
Name: PFM Medical, Inc.
Address: 1815 Aston Ave, Suite 106
Carlsbad, CA 92008

CONTACT PERSON: SALVADORE F. PALOMARES, RAC
PHONE NO: 760.758.8749

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K122402
Trade Name: Low Profile Port
Common Name: Port & Catheter, Implanted, Subcutaneous, Intravascular,
Classification: LJT 21 CFR 880.5965

Equivalent Device:
Manufacturer: PFM Medical, Inc.
Name: Jet Port Plus HP Catheter System
510(k) #: K072481

Device Description:
The Low Profile Port is an implantable device designed to provide repeated access to the vascular system without the trauma associated with multiple vena puncture. The system consists of a self-sealing injection port and a delivery catheter for the receipt and delivery of medications to the selected body site.

The Low Profile Port has a polyoxymethylene body, with or without a titanium insert and a silicone septum.

The base of the port has the letters "CT" to signify that it can be used for power injection on contrast agents. These letters can be visualized through a Scout CT. The lot number is laser etched into the base of the port. The port can be anchored with sutures in the port pocket for secure seating. The suture holes may contain clear silicone to prevent tissue in growth to the suture holes.

The Low Profile Port is offered with the polyurethane catheter either pre-attached by the manufacturer or attachable for application by the inserting physician. The catheter

lock provides securement of the catheter to the port. Introduction of solution into the implanted port and catheter system is through a non-coring needle.

Power injection of contrast media, can be safely administered with a 19 or 20 gauge power injectable infusion non-corning needle at a maximum recommended infusion rate of 3ml/sec or a 22 gauge power injectable non-coring needle at a maximum recommended infusion rate of 2 ml/sec. Maximum pressure should not exceed 300 psi.

The Low Profile Port is packaged with the necessary accessories to facilitate catheter insertion.

The port and catheter uses the same components and are manufactured and sterilized at the same manufacturing and sterilization facilities as the predicate device cleared under K072481. The power injection capability is comparable to the currently marketed Jet Port Plus HP Catheter cleared under K072481.

Components will be assembled into standard configurations or configurations specified by the customer and packaged.

The device includes the following components:

• Implantable Port	• Catheter
• Click Connector	• Huber Needle
• Guide Wire	
• Dilator	• Instructions for Use
• Tunneling Needle	• Nurses' Guide
• Vein Lifter	• Companion Checklist
• Introducing Needle	• Patient Guide
• Peel Away Sheath	• Patient Chart Sheet
• Syringe	• Patient ID Card and Key Ring Card

Intended Use:
The Low Profile Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, IV fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the Low Profile Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 3 ml/sec with a 19G or 20G non-coring power injectable needle or 2 ml/sec with a 22G non-coring power injectable needle.

Technological Comparison to Predicate Devices:

New device is compared to Marketed Device?

Yes. It is compared to predicate PFM Jet Port Plus HP Catheter System (PFM Medical, SE-K072481)

Does the new device have the same indication statements?

Yes; but the Low Profile Port has a lower maximum profile infusion rate of 3ml/sec. vs. 5ml/sec. maximum flow rate for the Jet Port Plus HP Catheter System.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)?

No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Yes. The Low Profile Port is identical to that of the Jet Port Plus HP Catheter System (SE-K072481). The devices are made by the same company PFM Medical CPP SA. The Low Profile Port is substantially equivalent to the predicate device, Jet Port Plus HP Catheter System (SE-K072481). The basic fundamental scientific technology of the device has not changed.

Could the new characteristics affect safety or effectiveness?

No.

Do the new characteristics raise new types of safety and effectiveness questions?

No.

There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95 was used to determine the appropriate methods for evaluating the device's performance.

- Sterilization requirements of ISO 11135:2007, Sterilization of Health Care Products - Requirements for Validation and Routine Control -- Ethylene Oxide Sterilization were met.
- Biocompatibility requirements according to of ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. Test profiles for externally communicating, blood-contacting, long-term devices were met.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics?
Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

Do performance data demonstrate equivalence?
Yes. Performance data gathered in design verification testing demonstrated that the Low Profile Port is substantially equivalent to the noted predicate device.

CONCLUSION:
The Low Profile Port met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the Low Profile Port is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate devices: Jet Port Plus HP Catheter System (PFM Medical, SE-K072481)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2013

PFM Medical, Incorporated
Mr. Salvadore F. Palomares, RAC
Director of Regulatory Affairs
1815 Aston Avenue, Suite 106
CARLSBAD California 92008

Re: K122402
Trade/Device Name: Low Profile Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Port & Catheter, Implanted, Subcutaneous & Intravascular Infusion
Regulatory Class: II
Product Code: LJT
Dated: June 21, 2013
Received: July 12, 2013

Dear Mr. Palomares:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K122402

Device Name: Low Profile Port

Indications for Use:

The Low Profile Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, IV fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ _____ Over the Counter Use
(Per 21 CFR 801.109)

Sajjad H. Syed

(Division Sign-Off)

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number K122402